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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,707

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Kazumori Funatsu

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EXAMINER

NAFF, DAVID M

ART UNIT

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1657

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,707	Applicant(s) FUNATSU ET AL.	
	Examiner David M. Naff	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A response of 3/26/08 to a restriction requirement of 1/3/08 elected Group I claims 1-17 without traverse, and canceled non-elected claims 18-29.

Claims examined on the merits are 1-17, which are all claims in the application.

5 ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15 Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20 The specification is unclear how the method described produces hollow fibers having in hollow portions a cell aggregate having cells formed in two or more layers in arbitrary directions with a distance from an arbitrary point of the cell aggregate to the nearest inner wall of the hollow fiber less than 75 μm . The procedure described in the specification of injecting cells into the hollow portion, using centrifugal force or hydrostatic pressure to pack the cells at high density, and culturing to obtain a cell aggregate (pages 34-37, and Example 1 (pages 38-41)) does not contain a step and/or condition that would result in the aggregate having two or more layers in arbitrary directions having a distance from an arbitrary point of the cell aggregate to the nearest inner wall of the hollow fiber less than 75 μm . From the description, the specification is unclear how a cell aggregate is formed containing two or more layers. There is seen nothing that would separate the cell aggregate into distinct layers. Additionally, there is

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seen nothing in the method that would result in a distance between the cell aggregate and inner wall of the hollow fiber to be a distance encompassed by less than 75 μm . From the description, the method results in the hollow portion filled with a cell aggregate without multiple layers and without a space between the aggregate and an inner wall.

5

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15

In line 2 of claim 1 and where recited in any other claim, "membrane type" is uncertain as to meaning and scope. A "type" of membrane is relative and subjective.

Claim 1 is confusing and unclear by claiming the cell-filled device in the preamble (lines 1-4) and then again claiming the device in lines 5-10 in more specific terms. This is claiming two different devices, one in terms broader than the other. Only one device is claimed.

20

In line 4 of claim 1 and where recited in any other claim "characterized in that" should be changed to --- wherein --- to positively claim the device. The device structure should be claimed rather than character of the device.

25

In lines 1-2 and 5 of claim 1 and where required in any other claim, "modified cross section" and "modified cross sections" is uncertain as to meaning and scope. The difference between a cross section modified and a cross section not modified is uncertain since the claim contains no limitation of how the cross section is modified.

In lines 8-10, claim 1 is unclear as to the distance from an arbitrary point to the nearest inner wall since the location of the arbitrary point and nearest inner wall are not specified. Additionally, there is not clear antecedent basis for "the nearest inner wall".

5 In lines 6-10, claim 1 is unclear as to physical structure of a cell aggregate containing two or more layers in arbitrary directions provided with a distance from an arbitrary point of the cell aggregate to the nearest inner wall of the hollow fiber less than 75 μm since the specification is unclear how such a structure is formed by the method described.

10 Dependent claims are unclear by the preamble repeating structure required by claim 1 that is not needed in the dependent claims since the structure is already required in claim 1. A dependent claim should set forth how a previous claim is further limit rather than repeat structure that is already required in the previous claim. For example, the preamble of claim 1 should recite "A cell-filled device according to claim 1, wherein". The preamble of other dependent claims should be similarly changed.

15 Claim 3 is unclear as to the meaning of "membrane is in a flat form". If a membrane is flat, the membrane will not contain a hollow portion.

Claims 4 and 5 are unclear by not having antecedent basis in claim 1 for "pore size". Claim 1 does not require the fiber membrane to have pores. Additionally, is the pore size the size of the hollow portion of the fiber, or is the size of pores in the membrane of the fiber in addition to the hollow portion?

20 In line 4 of claim 6, the meaning and scope of "polymer having a contact angle of 70 degrees or less" is uncertain. What is polymer structure that is a contact angle?

Claims 15 and 16 are unclear how the device claimed differs from that of claim 1 since the claims contain no structure for the device in addition to structure required by claim 1. Being for a hybrid artificial organ in claim 15 does not change the structure of the device from that in

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claim 1. In claim 16, the hybrid artificial organ can be the same as the device of claim 1 since no structure for the organ is required in addition to structure of the device.

Claim 17 is unclear as to structure of the hybrid artificial organ since a clear relationship between structural components of the organ has not been set forth. Additionally, in the last three lines, the meaning is unclear of "inside of a hollow-----is separated from an external of the hollow forming a communication path of the liquid to be treated".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

10

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15

Claims 1, 2 and 4-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Funatsu et al (6,284,451).

The claims require a cell-filled device comprising a hollow fiber containing a cell aggregate formed into two or more layers in arbitrary directions provided that a distance from an arbitrary point of the cell aggregate to the nearest inner wall of the hollow fiber is less than 75 μm . Also claimed is a hybrid artificial organ containing the device.

20

Funatsu et al disclose using centrifugal force to fill a hollow fiber membrane with cells such as hepatocytes, and culturing the cells in the hollow fiber to form a cell aggregate. For example, see col 4, line 50 to col 11, line 4. The hollow fiber containing the cell aggregate can be used to form a hybrid artificial organ (col 2, line 47).

25

The hollow fiber containing a cell aggregate disclosed by Funatsu et al is a cell-filled device the same as presently claimed. The cells in the cell aggregate of Funatsu et al are inherently in the form of two or more layers as claimed with the cell aggregate being a distance

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from an inner wall as claimed. The hollow fiber of Funatsu et al inherently has a modified cross-section as claimed since the inner diameter can vary (col 5, lines 15-20 and paragraph bridging cols 6 and 7). The membrane fiber of Funatsu et al inherently has a pore size as required by claims 4 and 5, a polymer contact angle of claim 6, polymers as required by claims 7-9, cells as required by claims 10-13 and sealed ends as required by claim 14. The hybrid artificial organ of Funatsu et al is the same as presently claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Funatsu et al.

The claim requires the hollow fiber membrane to be in flat form.

25 Funatsu et al is described above.

It would have been obvious to provide the hollow fiber of Funatsu et al in flat form to enable placing fibers closer together in a smaller space when less space is available for multiple fibers.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications
10 may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you
15 would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit 1657

DMN
7/29/08